Ensuring the Quality of Data Disseminated by the Federal Government

Workshop Report

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

Ensuring the Quality of Data Disseminated by the Federal Government

Workshop Report

Ad Hoc Committee on Ensuring the Quality of Government Information

Science, Technology, and Law Program

Policy and Global Affairs

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

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David Korn and Alan Morrison
Cochairs

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Introduction

Since the time of its founding, the federal government has disseminated important information to the public, primarily as paper copies of documents.[1] With the advent of the Internet, the volume of this disseminated information has grown considerably. Congress has encouraged this process through statutes that describe particular dissemination activities, as have circulars of the White House Office of Management and Budget (OMB).[2]

As the volume of government information has increased, so have efforts by various groups to challenge the sources of that information, especially when it is used for regulatory or other rule-making activities. These challenges, in turn, have prompted more formal action to ensure the accuracy of information used by government agencies.

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[1]Thousands of statutes mandate agencies to disseminate information of various kinds. Such dissemination is of long standing and fundamental to how the operations of the U.S. government are made transparent to its citizens. It also reflects the belief that if the government spends money collecting information it generally should make that information available to the public. For this reason, agencies had already developed mechanisms and procedures to guide their dissemination practices and to ensure quality control.

[2]See for example, OMB Circular A-130, "Management of Federal Information Resources," and OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations." OMB Circulars are instructions or information issued by OMB to federal agencies. The Office of Management and Budget oversees federal regulation, the budget, information collection and dissemination, proposed legislation, testimony by agencies, and other related activities.

In the fall of 2000, Congress enacted the Data Quality Act, directing OMB to issue, by September 2001, government-wide guidelines to "provide policy and procedural guidance to federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies...."[3] Accordingly, OMB issued proposed guidelines in June 2001, sought public comment, and issued revised guidelines in September 2001, seeking additional public comment. Final guidelines were issued in January 2002.[4]

The proposed OMB guidelines applied to information dissemination activities that vary in importance and scope, include all media (printed and electronic), and direct agencies to develop procedures that are consistent with their own missions, resources, and administrative practices. The proposed guidelines also:

- stated that "agencies shall have a basic standard of quality (including objectivity, utility, and integrity) as a performance goal";
- recognized a range of importance for government information, and asserted that more important information, such as "influential scientific, financial, or statistical information," should be held to a higher quality standard, with scientific or statistical results required to be "capable of being substantially reproduced";
- required that agencies disseminating information regarding risks to human health, safety, and the environment either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996;
- required agencies to establish administrative mechanisms that allow affected persons to seek correction of information disseminated by the agency, as well as to establish an appeals process;
- were designed to provide agencies flexibility in incorporating existing policies and procedures into the new guidelines; and
- were designed to assure maximal usefulness of the information to the intended users.

OMB received approximately 100 comments from academic institutions and societies (including the National Academy of Sciences), federal agencies, industry groups, individuals, and others on their proposed guidelines. While several agencies noted that they would be able to com-

[3]Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554).

[4]"Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies," January 3, 2002, 67 FR 369 and corrected version, February 5, 2002, 67 FR 5365, pp. 8452-8460.

ply with the guidelines by building on existing agency systems, the majority of comments focused on two aspects of the proposed guidelines: 1. the need to clarify definitions and terms, in particular the meaning of "influential scientific or statistical information" and "capable of being substantially reproduced"; and 2. the need to place limitations on the administrative correction mechanism.

The research community, in particular, expressed concern that the new guidelines might add additional expense for compliance, jeopardize the security of intellectual property, be misused by those who oppose research for any reason, and otherwise weaken the performance of research. Researchers also expressed a desire for a more precise definition of "influential information" in the context of science, as a result of OMB's interpretation of the statutory language, which went beyond what Congress had stated and included "scientific" in the category of influential information. Following expressions of concern from within the research community and a request made by OMB, The National Academies Science, Technology, and Law (STL) Program established an ad hoc committee to organize and host three workshops at which federal agencies that are subject to the guidelines could share their views and listen to ideas and concerns from other parties. The workshops were not intended to produce recommendations, but to assist agencies in developing their own agency-specific guidelines.

This document provides a brief summary of the key issues raised during the presentations and discussion periods at all three workshops. It does not attempt to summarize the entire three days discussions. Chapter 2 summarizes the workshops held on March 21-22, 2002, which focused on the OMB guidelines prior to issuance of agency-specific guidelines. Chapter 3 summarizes the workshop held on May 30, 2002, which focused on the draft versions of the agencies' guidelines. The order of presentations has been modified slightly to present a more logical sequence of topics. The transcripts from each workshop can be found at www.nationalacademies.org/stl.

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Overview of OMB Guidelines and Agency Concerns

The first workshop began with a keynote address by Dr. John D. Graham, administrator of the Office of Information and Regulatory Affairs at OMB, the office responsible for developing the government-wide Data Quality Guidelines.

THE OMB PERSPECTIVE

Dr. Graham said that federal agencies have disseminated information for decades, but usually in the form of paper documents. The Internet has increased the volume of information disseminated, he said, raising the difficulty of ensuring high quality. As discussed in the Introduction, the increase in information was also accompanied by more challenges to rules based on the information and requests to examine the "raw" data on which rules were based. The Data Quality Act of 2001 was an attempt to meet these challenges. While the original bill called for government-wide rules, the OMB insisted on guidelines instead.[1]

Dr. Graham noted, "There is plenty of evidence that the quality of information advanced for use by government decision makers needs to be improved. In the scholarly literature in the field of what is sometimes called science policy there are entire books of case studies demonstrating

[1]Guidelines are non-binding norms. Rules are developed under the Administrative Procedures Act, and require an agency to provide notice and invite public comment. Ordinarily, rules are binding on both the agency and the public.

technical problems with the information collected, used and published and released by the federal agencies." Dr. Graham cited recent studies by the National Institutes of Health and the Environmental Protection Agency in which results had been fabricated, misread, or poorly analyzed.

Dr. Graham stated that the Bush Administration is "committed to vigorous implementation of the new information quality law" and that the Administration believes it "provides an excellent opportunity to enhance both the competence and accountability of government." To fulfill this opportunity, the guidelines "imposed three co-responsibilities upon all federal agencies":

1. Agencies must commit to a basic standard of quality for the information they disseminate.
2. Agencies must develop information management procedures to prevent dissemination of poor-quality data, with peer review playing an important role.
3. Agencies must have an administrative mechanism that allows "affected parties" to request corrections of information. The burden of proof, Dr. Graham noted, is on the requester to demonstrate that the information fails to meet OMB or agency guidelines. If the request is denied, there must be an appeals process.[2]

Dr. Graham acknowledged that a number of concerns had been raised about the guidelines:

1. *The guidelines subject government information to a higher standard than information generated by industry, academics, and public interest groups*. Dr. Graham noted that a closer reading of the guidelines would suggest a more "nuanced" conclusion. "If a government agency wishes to rely upon and cite information from industry to support a decision, that information, because it becomes a dissemination, must meet the same quality standard that information generated by the agency must meet."
2. *The guidelines are unfunded mandates on agencies*. It is true that agencies will need to spend time responding to requests, Dr. Graham said, but the guidelines allow them to reject complaints that are groundless. He also estimated that agencies would probably save money in the long run.
3. *Original data may not be available*. Dr. Graham said the OMB was "reluctant" to require that all original data be reproducible, instead they require that analytical results (i.e., those derived from original data) be

[2]Graham cited this responsibility as "perhaps the key provision."

reproduced. "Show me what numbers or assumptions you have used," he said, "and how they add up to the number you say they add up to."

4. *Agencies may be reluctant to acknowledge that "affected parties" are truly affected*. He said that unless there was an objective appeals process inside agencies, "I predict there will be efforts down the road to make a mechanism that works from the outside."[3] He also said, however, that "the burden of proof is squarely on the affected parties. They must demonstrate that a specific dissemination does not meet the quality standards in the OMB guidelines or the agency-specific guidelines."

Dr. Graham said that OMB's focus would be on the design and implementation of agency procedures rather than on mediating disputes. He said he hoped the courts would refrain from intervening, but that it would "probably take some court decisions to know how they will be interpreted…" Acknowledging the challenge the guidelines present to the agencies, Graham concluded his remarks by saying "Our shared objective is an improvement in the quality of the information that the federal government disseminates to the public."

DISCUSSION

A brief discussion period followed Dr. Graham's presentation, with Mike MacCracken of the Office of the U.S. Global Change Research Program asking how projections made for many years in the future might comply with data quality guidelines. Dr. Graham said that agencies making projections or risk assessments would be asked to demonstrate their models and make them transparent enough to allow others to repeat the calculations.

Kevin L. Bromberg of the Small Business Administration asked if an agency that relied on "third-party data"—from outside the agency—would have to provide the underlying data. Dr. Graham said that if an agency disseminates information in an official way, "then they do have a responsibility to assure that that information meets relevant quality standards in the agency guidelines and the OMB guidelines." Whether it was possible to obtain the original data would be decided in the same way as for information disseminated by an agency, noted Dr. Graham.

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[3]Some participants noted that "affected parties" are not defined in the guidelines, creating a potential source of confusion. See, for example, question 4 posed by Frederick Anderson under Administrative Correction and Appeals, p. 20.

KEY GUIDELINE COMPONENTS AND CONCEPTS

Alan Morrison, a member of the Public Citizen Litigation Group and currently a visiting professor at Stanford University Law School, continued the introductory session by offering a synopsis of the basic components and concepts of the OMB guidelines.

In his opening remarks, Professor Morrison noted "…the message seems to be pretty clear that information is power in itself and it is important in and of itself quite apart from its use in the regulatory context … that government information is powerful because it has been disseminated by the government and people do and do not do things based upon what government information, as information, says…" Morrison also noted that "perhaps the most poignant example of the power of government information is the recent information about the value of mammography. Millions of women in the United States acted based on that [information]…"

What Kinds Of Information And Data Are Covered Under The Guidelines?

Under the guidelines government information is "broadly defined" and under the statute "it is required to be of high quality." The OMB guidelines cover many types of information, said Professor Morrison, and all kinds of formats and media. The guidelines pay special attention to factual information, specifically "influential" scientific, financial, and statistical information. One significant exclusion is for "opinion information." However, noted Professor Morrison, "I warn everyone to be careful about this exclusion. It would be in my judgment improper for an agency to say, 'Well, this is all our opinion, and therefore we don't have to pay any attention to the statute and guidelines.'" An agency should not assume it can "disseminate opinion after opinion without paying attention to the statute." He cited the analogy of libel law and its attendant difficulties. Libel law also attempts to draw a distinction between fact and opinion, but such distinctions are often questioned or hard to discern.

Professor Morrison noted a "non-inclusion" in the guidelines for press releases. However, he cautioned agencies to be careful because some press releases may be "chock-full of data" or include fact sheets, leaving the possibility for confusion. Morrison cautioned the agencies that "this is not a matter of semantics. It is not a matter of labels. The statute has a purpose and it requires that you be realistic in your assessment of what is in and what is outside of the guidelines."

What Is Dissemination?

Professor Morrison said that the OMB guidelines apply not to the collection or maintenance of data but to its "dissemination by federal agencies." He defined dissemination as public distribution or sharing of information by an agency—by printed, electronic, or other means. The OMB guidelines take special note of the Internet, which both "enables agencies to communicate information quickly and easily to a wide audience" and also "increases the potential harm that can result from the dissemination of information that does not meet basic information quality guidelines."

Many uses of information are not considered dissemination if they are intended for a limited audience or a specific setting. Professor Morrison suggested the following examples of information use that are not acts of dissemination: a response to a FOIA request; a response to a letter; and information provided during adjudication. However, he noted, once an agency posts information on its Web site, it is disseminated—even if its initial intended audience was limited.

He also said that information produced by grantees or employees of an agency does not become "of the agency" unless it is adopted and disseminated by the agency. He suggested that publications or Web postings resulting from research supported by a federal agency should contain a disclaimer to the effect that the views are those of the individual, not the agency.

Professor Morrison clarified that agencies must not wait until the time of dissemination to ensure data quality. High quality should always be a priority because an agency cannot know when certain data may be used in regulation or rule making—even long after the work is done.

He noted that the OMB guidelines take effect on October 1, 2002. Any information disseminated after that date is covered by the guidelines. Information disseminated prior to that time does not have to be reviewed under the guidelines. However, if older information is challenged, the agency may bear the burden of reconsidering that information in light of the guidelines.

What Is "Influential" Information?

The Data Quality Act suggests that there are two types of data: (1) data that are "important" (an OMB term) and/or "influential" (an Act term), and (2) all other data or information. The Act says that a higher standard of quality applies to influential information. As defined by OMB, "influential scientific, financial, or statistical information" is of such high importance "that the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on

important public policies or important private sector decisions." This definition contains several changes from earlier versions; "clear and substantial," for example, was added "to reduce the need for speculation on the part of agencies." "Financial" information also has been added as an example of potentially influential information.

Professor Morrison made five key points about influential information:

1. It is not necessary to put a label on all disseminated information. "You don't have to say that this is influential or this is not influential." Agencies may want to make an internal determination about what is influential, but the difference between what is or is not influential is only of importance under the guidelines if someone complains about the information.
2. It is important to focus the question of whether something is influential on the information itself. "That is, is the information influential, not is the ultimate decision on which the information is based in part going to be influential."
3. The "clear message of the guidelines is that most information that agencies disseminate is not influential information."
4. The key aspect of data being categorized as influential information "is that it must be reproducible." This doesn't mean that the agency must actually reproduce the information in order to disseminate it, but rather it means that the information is "capable of being reproduced."
5. The question of whether information is influential may change from the time the agency originally disseminates it until the time the agency actually uses it.

What Is the Complaint Mechanism?

Professor Morrison noted that while under the Administrative Procedures Act, the public has the right to complain about the quality of agency data, the OMB guidelines strengthens that right by requiring that the agencies respond to the complaint. "The agency has to respond, and not only does it have to respond, but at the end of the year it has to send OMB a report explaining what kinds of complaints it received and what kind of responses it gave."

When receiving a complaint, the agency has to decide whether to have someone with a completely unbiased view of the information, who had no responsibility for the preparation or dissemination of the information evaluate the complaint or whether to have someone intimately familiar with the information assess the complaint. If the agency's response to the complaint is not satisfactory, the agency must provide the filer with an opportunity to appeal. Professor Morrison noted that "the choice of the

appeal process OMB makes quite clear is up to the agency and the agencies may well want to have a multi-person appeal process to be able to bring in both some objectivity and some knowledge and some more general kind of expertise in information dissemination."

DISCUSSION

Following Professor Morrison's overview, a number of questions were raised. Harold Halpern of the Department of Energy asked if agency advisory committee reports were covered by the guidelines. To which Professor Morrison responded, "My own view is that the advisory committee…. would be like outside researchers … It is an outside submission. Indeed the whole purpose is to get outside advice and my view is that the agency is not responsible because after all it doesn't control it." Professor Morrison, noted however, that if the agency takes the results of the report and "then issues a regulation or approves a product … and disseminates [the report] and says that this is the basis on which we are acting, it has in my judgment adopted it as its own and subject to some obvious practical limitations has got to make reasonable assurances that it is accurate."

Ray McAllister, CropLife America, asked about information that is released to an individual under FOIA that is posted on an Internet site. Professor Morrison noted that while the information may have influence, "I do not believe that the statute puts the burden on the agency to worry about what somebody else may do with the information."

DETERMINING THE THRESHOLD-INFLUENTIAL SCIENTIFIC, STATISTICAL, AND FINANCIAL INFORMATION

Richard Merrill, Professor of Law at the University of Virginia, moderated a panel discussion on agency approaches to determining influential information. The panel comprised Nancy Kirkendall, Energy Information Administration of DOE; Steven Galson, FDA; and Fred Siskand, DOL. Prior to the agency representatives discussion, Richard J. Pierce of The George Washington University Law School provided his perspective on how best to categorize influential data.

Mr. Pierce indicated that he found the definition of influential information[4] to be unclear, stating that of 100 different types of information an agency disseminates he could probably identify 2 or 3 types

[4]"Scientific, financial, or statistical information the dissemination of which will have or does have a clear substantial impact on important public policies or important private sector decisions," as stated in the OMB Guidelines.

that are definitely influential, 2 or 3 that are definitely not, but would be hard press to know if the other 94-96 types were influential. They probably could be argued both ways. Mr. Pierce stated that this should be viewed as a "very important opportunity." "The malleability of the definition leaves you a tremendous amount of discretion to figure out what you want to call influential information and I would urge you to think very, very carefully about what you want to call influential…" The reason, he said, is that in designating an action as influential, agencies might "create a legal regime" in which each dissemination of that type of information becomes immediately reviewable as final agency action. Mr. Pierce closed by urging agencies to identify only a very few things as influential.

During the agency presentations, Nancy Kirkendall of the Energy Information Administration of the Department of Energy, said that her agency focuses on "high-quality, policy-relevant information to support public and private decisions." Most of this work is statistical, she said, and virtually all of it conforms to high standards of transparency and reproducibility. Thus it has, by its nature, already acquired the OMB's criteria for influential.

Dr. Kirkendall agreed that if data are influential, "you need to have a high degree of transparency." She said that the statistical information her agency produces is "already transparent" because of procedures worked out over the years.

Dr. Kirkendall noted that for statistical agencies, good practice means that products are transparent and reproducible, "or at least if we follow our own guidelines they are. If you have a question about a number, we can find out exactly what information went into that number."

Steven K. Galson of the Food and Drug Administration said the FDA proposed defining "influential" information as "economically significant, as defined in Executive Order 12866: any rule-making action that will have an annual effect on the economy of $100 million or more or will adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety or state, local and tribal governments."

Fred Siskind of the Department of Labor said that the DOL's diversity of products is "almost overwhelming," as is its total number of documents. His department has posted over 200,000 documents on its Web site. By using the screens suggested by the guidelines, however, he said that a very small percent of disseminated information would fall under the "influential" category. Some examples of DOL influential information include the Consumer Price Index, Producer Price Index, and other national economic indicators. He said that DOL was still working on its definition of influential.

DISCUSSION

During the discussion period, Robert Ashby of the Department of Transportation commented that DOT would define "influential" as being "outcome determinative of a key issue." He also noted that the government is not only a generator of information, but also a "considerable recipient" of information, and that DOT would want to determine which of the incoming information should be classified as influential.

Dr. Carla Steinborn of the National Oceanic and Atmospheric Administration noted that most information released by her agency—such as weather forecasts—was difficult to regard as "influential" when released, but could become so later, triggering a call for reproducibility. In most cases, she said, this could not be done for NOAA research, and she said her agency had not yet resolved this problem.

THE STANDARDS OF TRANSPARENCY/REPRODUCIBILITY/ PEER REVIEW FOR INFLUENTIAL INFORMATION

The OMB guidelines direct agencies to develop procedures for reviewing and substantiating "the quality (including the objectivity, utility, and integrity) of information before it is disseminated." The guidelines characterize quality as the "encompassing term," and the others are "constituents," with the following meanings:

- **Utility** refers to the usefulness of the information to the intended users.
- **Objectivity** focuses on whether the disseminated information is accurate, reliable and objective, and is presented in an accurate, clear, complete, and objective manner.
- **Integrity** refers to the protection of information from unauthorized access or revision.

Transparency

The OMB guidelines state that the concepts of utility and integrity are relatively straightforward and arouse little debate. Achieving objectivity, however, is less clear. The OMB guidelines suggests that to be objective, information should be produced by methods that are "transparent" and should be reproducible by others.

The goal of transparency for data and methods, according to the guidelines, is "to facilitate the reproducibility of such information." The guidelines add, "Where appropriate, data should have full, accurate, transparent documentation, and error sources affecting data quality should be identified and disclosed to users."

Reproducibility

A generally accepted standard in the world of research is that experimental results should be capable of replication by others. The guidelines originally stated: "If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties."

This statement stimulated much debate because some research may be difficult, expensive, or impossible to replicate. In practice, few experiments are replicated precisely, because of such obstacles as confidentiality, expense, irreproducibility of original data, and the death of persons who took part in the original research. For such reasons, the guidelines were modified to say the work must be "capable of being reproduced."

Types of Scientific Information.

The OMB guidelines list two types of "information" in the case of scientific studies. One is original and supporting data. The OMB urges caution in the treatment of such data because it may often be "impractical or even impermissible or unethical to apply the reproducibility standard to such data." As examples, the guidelines state that "it may not be ethical to repeat a 'negative' (ineffective) clinical (therapeutic) experiment and it may not be feasible to replicate, for example, the radiation exposures studied after the Chernobyl accident." Thus the guidelines urge agencies to consider "which categories of original and supporting data should be subject to the reproducibility standard and which should not," and that they should make this determination with the help of "relevant scientific and technical communities."

The second category is analytic data. OMB states that "reproducibility is a practical standard to apply to most types of analytic results." The guidelines add: "With respect to analytic results, 'capable of being substantially reproduced' means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error." The primary benefit, according to the guidelines, would be to allow the public to "assess how much an agency's analytic result hinges on the specific analytic choices made by the agency." The OMB guidelines also acknowledge that the "objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections."

Peer Review

Journals, granting agencies, and others traditionally seek transparency in research through peer review—qualified experts who review the research concept, methodology, and results. The OMB guidelines praise the mechanism of peer review for its general reliability; they also say that peer review is not fail-safe, and that the "competence or credibility" of the reviewers themselves is occasionally challenged. The guidelines state that peer review "is rebuttable based on a persuasive showing by the petitioner in a particular instance." The guidelines add that occasional cases of falsification of data have slipped through the process of peer review.

Michael R. Taylor, Resources for the Future, moderated a panel discussion regarding agency approaches to achieving objectivity. He opened the session by noting the "irony" of a law (the Data Quality Act) emphasizing transparency that was passed by Congress without a hearing process. The session began with comments by R. Brooks Hanson, *Science*, and Robert O'Keefe, HEI, who provided non-agency perspectives on these issues. Agency representatives, Heather G. Miller, NIH; Kevin Teichman, EPA; and John Rodgers, FAA, then followed with presentations on their respective agency approaches.

Dr. R. Brooks Hanson, Deputy Managing Editor for Physical Sciences at *Science*, offered a detailed description of how a leading scientific journal performs peer review. Reviewers are expected to consider whether the data and analytical methods substantiate the conclusions; whether interpretations are fairly presented; whether other hypotheses or conclusions should be mentioned; the level of statistical and other kinds of uncertainty; whether data are separated from conclusions; and whether the scholarship, referencing, and presentation are appropriate. He noted that in all the reviews he had seen, a referee had requested replication of data in only a very few cases. At the same time, he said, "peer review and publication fosters reproducibility. Any reasonable request for materials and methods must be made available... The goal of peer review is to evaluate or guarantee significance—both of the data and the interpretations and of each separately."

Dr. Robert O'Keefe of the Health Effects Institute said that HEI takes special pains with its "rigorous peer reviews…[as]…a key step for us and really for all the studies that we undertake." HEI maintains an independent standing committee of subject-matter experts, which exists solely to review the quality of HEI studies. Studies thought to have "significant regulatory impact" receive additional scrutiny, including quality oversight, detailed peer review, and extensive commentary on the study and its underlying data.

Dr. O'Keefe identified three groups of studies:

1. Contributing studies—the "rank and file" of information;
2. Studies likely to be relevant to regulation; and
3. Those few studies with known and significant regulatory impact.

In the last category, he said, were results that would be at the core of a regulatory outcome. These, and some studies from category 2, would certainly be influential. For these, he said, it is "reasonable for higher levels of detail to be expected." He added that it is not cost effective, however, to provide an extensive level of oversight for all studies.

Dr. O'Keefe said that transparency held high priority at HEI, as reflected in its research reports, which "are perhaps a bit unusual" in that they include all the data generated during the course of a study, the scientific methods used, and the range of approaches employed by investigators. He said that transparency was a founding precept of HEI, which is structured to promote objectivity in decision making.

For Dr. Heather Miller of the National Institutes of Health, the issue of transparency "is at the heart of how science is done and how the NIH does business, including the business of information dissemination." Dr. Miller said that NIH could move relatively quickly toward compliance with OMB guidelines because "the agency has always controlled the quality of the information it presents, and inherent in the process of assuring quality is peer review. It is a very slight modification of the way we have always done business."

Dr. Kevin Teichman of the Environmental Protection Agency said that the criteria for defining transparency are found in EPA's risk characterization handbook, which requires description of the approach one is using, the assumptions made, models used, where data gaps exist, where one extrapolated from the data, what the uncertainties are, where one is using data or relying on defaults, and where one is making scientific conclusions as opposed to policy decisions.

The EPA, according to Dr. Teichman, has had a peer-review policy in place since June 1994. It requires that major scientific and technical work products be peer reviewed, with external peer review used for work products that support important decisions. The EPA peer-review handbook was revised in December 2000, providing the guidance for implementing the peer-review policy.

Dr. Teichman said that the EPA also was contemplating the use of the "economically significant" standard, as well as the case-by-case approach being considered by the Department of Labor. He said that EPA might give the OMB guidelines to those submitting third-party studies that may at some point become influential information.

Dr. Teichman said that an unresolved issue for EPA was how its guidelines should address information generated by third parties that

may or may not be reproducible. In the pesticide program, for example, the agency receives hazard information from pesticide suppliers. He raised the possibility of proactive steps, such as requiring third parties to adhere to the guidelines.

Mr. John Rodgers of the Federal Aviation Administration said that the FAA deals with several categories of "influential" information, including those related to the development of airports, making financial decisions regarding airports, and regulating other aspects of transportation.

Mr. Rodgers approved of the use of transparency as a criterion, and said it should allow the reader to know what data, assumptions, analytical methods, and statistical procedures were used. He noted that "in general the information that the FAA uses tends to be transparent and I think we are compliant in spirit."

With respect to peer review, Mr. Rodgers described the compliance of FAA as "mixed." "I think for all types of data there is something I could characterize as peer review, although it is not necessarily done with respect to a uniform set of standards or guidelines, and it is not necessarily always documented in the same way." He also said that using the same external peer reviewers, who know the programs, could lead to conflicts of interest. He said he was curious to see whether the agency would move "peer review outside the scientific community and into the operating context where the FAA operates, how successful we will be in creating entities to do peer reviews."

Earlier in the workshop, Dr. Steven Galson said that the FDA strives for a high degree of transparency in the high volume of health-related information it disseminates publicly, including risk notices, rule-making documents, product approvals, guidance and regulatory assistance, and reports. FDA is developing new templates for all drug reviews to ensure that they are written in a consistent way across different classes of drugs and by different reviewers.

The Bureau of Labor Statistics, said Dr. Fred Siskind, already has to meet certain OMB requirements in the area of generating statistical information, and these would likely meet the guideline requirements. He said that BLS puts out descriptions of its methodology, making the process transparent and—in theory—reproducible. He said that BLS does have privacy and confidentiality concerns, and does not give out data about individual people or establishments.

DISCUSSION

Mr. MacCracken of the Office of the U.S. Global Change Research Program asked Dr. Hanson how he would handle situations where the criteria for objective peer review were not met by the reviewers. Dr.

Hanson said that *Science* asks all reviewers to describe potential conflicts of interest, both financial and intellectual, and that part of the editor's job is to know the pool of potential reviewers. Dr. Miller added that NIH has a huge peer review operation to screen applications, and that financial conflict of interest "is one of the points that we explicitly have each reviewer address prior to any round of review... We also vet reviewers for personal conflicts, such as, is this person your best friend or worst enemy."

Ray S. McAllister of CropLife America cited the concern that occasionally an agency would reach into the open literature for information in making a pesticide decision and use studies that, even though peer reviewed, are of lower quality than data produced by pesticide manufacturers themselves. Dr. Teichman of the EPA responded that "we would certainly hope that all of the data the agency would use would follow the best possible practices, good laboratory practices and others that would comply with the OMB data quality guidelines."

Dr. William Perry of OSHA said that the "testimony of experts can be really critical" in setting standards, and that OSHA works closely with national consensus standard organizations like ANSI and ASTM. He said that consensus standards are often the starting point in areas where "you won't find a lot of peer-reviewed science."

Dr. Galson said that the FDA also relies on data from outside firms in making many decisions, and much of that data are confidential business information closely held by the sponsors. He considered "our review process of this data to be the peer review of the data that is submitted." However, he said, "for certain drug approvals we do go to scientific advisory committees for recommendations."

RISK INFORMATION REGARDING HUMAN HEALTH, SAFETY, AND THE ENVIRONMENT

A category of information in which objectivity is viewed as very important concerns risk, which is discussed in the guidelines in the context of health, safety, and environmental information. Agencies making health- and safety-related decisions about risk are directed not only to use the best available data, but also to provide risk information about their decisions. This information should include such features (as specified in the Safe Drinking Water Act) as which populations are most affected by risk, the central risk for specific populations, appropriate upper- and lower-bound estimates of risk, significant known uncertainties in predicting health or safety effects, and studies that would help resolve these uncertainties.

Joe S. Cecil, the Federal Judicial Center, moderator of this session observed that risk assessment is "certainly the most demanding form of dis-

closure that is considered by the regulations and it has earned its distinction because of the especially contentious disputes that have taken place over the years." He noted that agencies must not only gather extensive information on risk, but do so in a way that ensures the timely flow of vital information to medical providers, patients, health agencies and the public—"a pretty tall order."

Starting off the presentations, Dr. Joseph Rodricks, Environ, reviewed an earlier report issued by the National Academies in 1983, called "Risk Assessment in the Federal Government: Managing the Process." He noted that many of the points in the OMB guidelines are anticipated in that study, which should serve as a useful guide in addressing current issues. He expressed some skepticism about whether it is possible to demonstrate that a complex risk assessment is capable of being reproduced.

Dr. William Perry agreed with the 1983 Academies report that risk analysis should include hazard identification, dose-response assessment, exposure assessment and risk characterization. "Those four things," he said, "require different kinds of information," including peer-reviewed literature and many other sources. At OSHA, he said, a risk assessment typically has two parts: (1) hazard identification and (2) exposure response. This relies heavily on peer-reviewed scientific studies, striving for best estimates of the size of the population at risk, estimates of how effective preventive measures are likely to be, and ways to resolve conflicting information.

At the Department of Labor, said Dr. Perry, OSHA rule making about health issues generally requires the agency to develop a risk assessment. The goal is "to determine the levels of risk for workers exposed to various chemicals" and to "estimate the impact of reducing exposure to those particular chemicals."

Dr. Perry also noted that the department has in the past used literature searches to establish standards, trying to determine the best studies that are peer reviewed and information on the methodology used to collect the data. "I often say that I used to think economics was a soft science," he said, "until I saw some of this stuff. It is not the hardest stuff in the world in terms of accuracy; there are lots of uncertainties, and often the underlying data just are not available."

Dr. Kevin Teichman said that EPA has a risk characterization handbook. Its policy for risk characterization came out in March 1995 and mandates that each risk assessment used in EPA decision making should include a risk characterization that bridges risk assessment and risk management. Risk characterization, he said, "is that integrating, summarizing step at the end of a risk assessment that puts the information in a form that the decision maker can use. It is very important for scientists to realize when they are conveying information about risk and when

they may be moving into the arena of providing information on risk management or on policy calls, and we try to very carefully draw the distinction."

Dr. Steven Galson said that much of the influential information disseminated by FDA is based on analyses of risk to the public of certain actions or exposure. Quantitative risk assessments may include health, safety, ecological, engineering, and physical hazards encountered during the use of medical devices, such as artificial hips, stents for heart arteries, and valves; food chemical residues; and antimicrobial resistance genes and bacteria. "Risk analysis is broadly used in the agency as a tool to enhance the scientific basis for all our regulatory decisions including product approvals," he said. But, he added, "many of our actions are essentially qualitative." For example, in the law that governs drug approvals, the standard for new drugs is that they be "safe and effective." These qualities do not have numerical thresholds. For these, FDA depends frequently on outside expert advice.

FDA proposes to adapt the general principles for risk assessments in the Safe Drinking Water Act (as stated in the OMB guidelines) to fit those situations. It proposes to define risk as the likelihood of injury and/or damage that can be caused by a substance, technology, or exposure. Dr. Galson added, "Although we analyze the economic costs of these regulations and consider alternatives, most of our regulations simply don't lend themselves to the type of quantitative risk assessments that are contemplated by the Safe Drinking Water Act principles."

In addition, many FDA actions are based on research and supporting data generated in biotech or drug companies. In these cases, approval actions are based on scientific studies conducted by sponsors that are seeking marketing approval in accordance with our regulations and our guidance documents.

DISCUSSION

Mr. Neil King of Wilmer, Cutler and Pickering asked how agencies chose among studies to support risk assessments when the studies give conflicting results, and "whether these guidelines are going to require any changes in the way you make selections among studies to use for purposes of risk assessment." Dr. Perry said that OSHA did indeed confront this dilemma. He noted that the guidelines apply only to information dissemination, so that OSHA focuses on how the act of disseminating that information is going to be changed by these guidelines. He noted that by the time OSHA makes a rule, it already has disseminated a great deal of information. He did not see the guidelines affecting how they look at information for setting priorities on major health hazards.

Administrative Correction and Appeals

The OMB guidelines oblige agencies to respond to complaints from people who are affected by agency decisions. They describe "affected persons" as those who may benefit from or be harmed by the disseminated information. The guidelines recognize that most agencies already have mechanisms to respond to complaints, but they now require agencies to respond directly to complainants and to itemize their complaint history for OMB at the end of each year. They also require each agency to add an appeals process for the benefit of complainants, with "appropriate time limits in which to resolve such requests for reconsideration."

A panel discussion, moderated by Frederick R. Anderson of Cadwalader, Wickersham & Taft and comprising Daniel Cohen, DOC; Neil Eisner, DOT; Eileen Stanley, EPA; and James Scalon, DHHS, highlighted key issues their respective agencies were wrestling with.

Mr. Anderson introduced a discussion of the corrections and appeals process with a series of procedural questions for the panelists and audience to ponder.

1. Time limits: Agencies must specify time periods for correction requests and appeals, but what should they be? What should be their own deadlines for responding to requests and appeals?
2. Can information be challenged at the moment of dissemination, before it reaches the policy or rule-making stage? Or must a challenge await the rule-making or policy-making step?
3. The guidelines for agencies apply specifically to information released after October 1, 2002. How should agencies handle requests for corrections of data disseminated before October 1, 2002?
4. The OMB guidelines stipulate that "affected persons" should be able to bring a challenge. Who is an affected person?
5. How should the corrections process proceed: Should requests be directed to the chief information officer (as the guidelines suggest) or to people with expertise on the information in question? Will a written response be required?
6. How should the appeals process proceed: How can it ensure the impartiality and fairness of sound law? Will it include independent third-party review? What kind of record of the initial discussion will provide a basis for appeal? Will the agency limit contact with the petitioner; the office that produced the data; the appellate agency; other petitioners?
7. For interagency information gathering or rule making, is there a mechanism short of an appeal to consult with other agencies that may be affected?

8. Will there be opportunities to be heard or to cross-examine during informational review process at the appeals level?

9. Will agencies seek outside expertise to develop appropriate, high-quality answers to appeals?

10. Forms of relief: Some agency responses will be non-controversial, including correction, retraction, or defense of data. Disclosure of the existence of multiple views might not be a sufficient response. Should a higher standard of quality apply during the appeals process? If the complaint is that the agency has insufficient data, should there be relief that requires extra work by an agency? Who would pay?

11. Judicial review: Will the courts impose judicial review in some case? This seems likely, because of the courts' tradition of overseeing the use of information that affects people's lives. Reviews already occur in the case of statutes overseen by agencies, such as EPA, where the courts have examined guidelines from the point of view of the challenger.

With regard to what is reviewable, Mr. Neil Eisner of the Department of Transportation said that "in my opinion the substance of our decision is reviewable under the Administrative Procedures Act. If we have incorrect data and somebody has pointed it out, the reasonableness of our response to them is subject to APA review."

Mr. Eisner also described the importance of deciding who receives the complaints. In DOT, he said, the initial response will probably be given by the experts responsible for the data. If there is an appeal, an appeals person or panel will be appointed that has an "appropriate balance between neutrality and enough knowledge to make the decision." For frivolous and repetitive complaints, he said that agencies appear to have the authority under the guidelines to reject them. The agency will probably ask for specificity in the complaint, why correction is needed, and where the data are incorrect. It will ask the challenger to file a complaint within 180 days of dissemination. The agency will respond to a complaint within 90 days and to an appeal within 45 days. The agency will ask complainants to state how they were harmed and how correction would benefit them.

Mr. Dan Cohen of the Department of Commerce noted an ambiguity. He said that "the statute talks about a review mechanism looking at agency compliance with the OMB guidelines—not actually whether the information itself is correct or incorrect, but whether the agencies complied with a process for developing that information."

Mr. Cohen noted that there is some confusion over legal standing, with some suggesting that affected and standing are equivalent. "I am not sure that is right. … You could be affected for purposes of this statute but not really have standing to challenge in court, and I think that agencies

should be very careful in deciding who is affected to make sure they don't blur the distinction."

Mr. Cohen also discussed relevancy. He indicated that "agencies should have the ability in their administrative mechanism process to be able to decide that correcting a particular item of information doesn't make any difference. So, why…bother…" Mr. Cohen illustrated this with a complaint that might come in stating that the Weather Service had predicted that yesterday's weather would be sunny and warm and instead it was raining and cold. Mr. Cohen asked, "… should the Weather Service even bother dealing with that as a request for correction?"

Ms. Elaine Stanley of the Environmental Protection Agency discussed the agency's web-based integrated error correction system that the agency was considering using as part of the data quality correction process. Under this system, an error is defined as a "deviation from accuracy or correctness and described as the difference between observed and/or approximately determined value and the true value of a quantity." Ms. Stanley noted that a key principle in managing any correction mechanism is knowing who owns the data. "Knowing who has the responsibility and the authority over the original data or more broadly the information is the No. 1 principle in terms of trying to get it corrected and resolved…"

In terms of the appeals process, Ms. Stanley stated that EPA was considering two options: (1) Affected persons would file the appeal with the assistant administrator or regional administration or (2) Affected persons would file the appeal with the chief information officer.

Mr. James Scanlon, Department of Health and Human Services, indicated that while honoring the existing processes and legal mechanisms for different agencies within the department, such as FDA and NIH, the department will try to establish a common template to be used by affected parties when making requests for correction. Scanlon indicated that DHHS is trying "to make it fairly flexible to request the correction," but emphasize that the affected person must be quite clear in describing what exactly needs to be corrected. With respect to appeals, Scanlon said that the appeal would go to one level above the originating office and could conceivably be raised to a higher level within the department if needed.

3

Draft Agency-Specific Guidelines

The following section includes descriptions of some preliminary draft guidelines developed by selected agencies, followed by several critiques by representatives of scientific organizations. All presentations were made at the third workshop on May 30, 2002.

SCOPE AND COVERAGE OF THE GUIDELINES

Department of Commerce

Lisa K. Westerback of the Department of Commerce said that Commerce had decided to apply broad "umbrella guidelines" to the agency as a whole, and develop specific guidelines or standards for each operating unit. The reason she cited was the "diversity of operating unit missions." The process was led by the chief information officer (CIO) and supported by a cross-department team. The CIO was to file an annual agency report on data quality to the OMB, while the operating units were to publish their own reports.

The agency also designed agency-wide standards for data quality and asked individual units to "adopt or adapt" these standards "where it makes sense," including statements on disclaimers, utility, integrity, and administrative mechanisms for corrections. Eventually, Commerce will use a single department standard for financial information, noted Dr. Westerback.

Dr. Westerback concluded that Commerce "is an information agency," and that "quality is already a hallmark of our information products. We didn't need this [process], but we welcome the opportunity to document it all."

Department of Health and Human Services (DHHS)

Mr. James Scanlon said that DHHS had used a process similar to that of the Department of Commerce, publishing its guidelines in two parts: a series of guidelines for the entire agency, and a draft or template to be adopted or adapted by each of the operating agencies and offices.

To create these guidelines, the HHS assembled a data quality working group under its Data Policy Council. This Council is responsible for overseeing the dissemination of substantive information by the agency, including:

- results of scientific research studies
- statistical and analytic studies and products
- programmatic and regulatory information, including program evaluations
- public health surveillance, epidemiological and risk assessment studies and information; and
- authoritative health, medical, and safety information initiated or sponsored by HHS.

The guidelines applied only to information initiated or sponsored by HHS, and bearing its imprimatur. They do not apply to extramural research, where dissemination is the responsibility of the investigator, or to intramural research published independently by the investigator. Mr. Scanlon further noted that "information" was defined as "any communication or representation of facts or knowledge, in any medium or form." Information did not include:

- distribution limited to government employees, contractors, or grantees
- opinions
- intra- or interagency use or sharing of information
- responses to FOIA, FACA, or the Privacy Act
- hyperlinks to data disseminated by others; and
- correspondence limited to individuals, press releases, archival records, subpoenas, or judicial proceedings

DISCUSSION

Professor Morrison said that there might be some confusion about what started out to be an OMB exemption for press releases, on the assumption that they constitute opinions rather than facts. He noted, however, that "we think that '*x* is a carcinogen' sounds very similar to '*x* is a

carcinogen.' " He advised caution when seeking a broad exemption for any kind of information, including press releases, testimony to congress, submission to states, or other communications.

A questioner asked for the rationale for issuing a disclaimer for information that is not disseminated. Dr. Westerback said that even within her bureau there were different policies regarding dissemination. When the Bureau of Economic Analysis published income and productivity information, such data were considered disseminated. If a BEA economist, however, publishes a paper under his/her own name, it does not necessarily represent the view of the agency and is not considered disseminated. The policy of NIST, however, is that information one of their scientists publishes represents the views of the agency and is disseminated.

Mr. Scanlon said that the presentation of papers by DHHS scientists is one of the ways the agencies regularly disseminate information.

Robert Ashby of the Department of Transportation said that for testimony to Congress, the political process already deals efficiently with inaccurate data. It would be superfluous to layer another procedural framework on this process through the Data Quality Act.

Professor Morrison said it seemed clear that congressional testimony is dissemination. A concern is that agency people called to testify on short notice may not have time to review the quality of their data.

A questioner asked whether a study concerning a controversial issue could be challenged before the study or the rule-making processes were complete. Dr. Westerback responded that the new law would not remove the regular rule-making process, which would remain the first priority.

A final question concerned whether the new law meant that an agency would be required to disseminate information that it was not otherwise planning to disseminate. Professor Morrison said that the guidelines did not appear to mean this or to apply to data an agency never planned to disseminate.

CORRECTION AND APPEALS PROCESS

Department of Transportation

Mr. Robert Ashby gave the results of a brief, informal survey he had conducted of other agencies:

- Most of agencies will require those who request a correction to fill in a standard fact sheet, including name, reason for the request, way in which the person was affected, and so on.
- Time frame: Most agencies will allow 30 to 90 days to file a request for correction, with 45 to 60 days the most common time limit. Agencies

will allow themselves 45 to 60 days to consider their response. The appeals process would use the same time frame.

- Who is an affected person? According to most agencies, it is a person who can show that he or she is harmed in some way, or would benefit from a correction of the information. One agency offered more detail: "someone who has suffered injury to a legally protected interest, who can show a causal connection between agency action and injury, and who can show that correction will correct the injury." An agency might rule that one person was not affected by a ruling, and would not receive a response, while it might rule that another person was affected by the same ruling and would receive a response.
- The issue of 'filters': The following conditions might filter out a response: the request does not pertain to disseminated information or "information" at all; the request is frivolous, trivial, or made in bad faith; the request is duplicative (e.g., one of many form letters, to which only one response is needed); it does not "state a claim"; or it disrupts agency operations.
- Who responds to the request? Many agencies said this would be the head of the unit that originally issued the information. In rule making, some agencies specifically said that a request for correction would be answered in the final rule or document rather than in a separate corrections process. The purpose is to avoid creating another layer on an already existing process.
- Is correction required? The agency may agree that some information could be improved, but would correct it only if it would serve a "useful purpose." Some corrections would require significant resources or might not advance the material interest of the public or the requester. "You don't want the correction process driving your budget," said Mr. Ashby.
- What is the standard for accepting an appeal? The statute specifies cases where information is not within an acceptable degree of error or precision. This loose definition has not yet been narrowed or tested.
- Who decides whether to respond to a request for an appeal? Many agencies said that this should be someone different from the person who received the original request for correction: possibly an associate administrator or an executive panel, probably of three people in order to maximize both expertise and objectivity.

Department of Education

Dr. Marilyn Seastrom said that the Department of Education had maintained written standards for information quality since 1992. In accordance with the OMB guidelines, they were adding an appeals process.

The correction process will begin with a consultation with a contact person for the "information product," which in some cases "may do away with need for correction." The next step would be a request for a correction by an affected person who thinks a product does not meet the guidelines. To make a request, a person would have to provide personal identification, describe the information (name, office/author, specific item); the potential impact of the error; what benefit would be achieved by correction; and reasons for the request (including elements of the guidelines not followed).

The request will then be reviewed for clarity and completeness. If the elements are in order, the request will be forwarded to the appropriate program office.

During a 60-day response period, the program office may issue a request for clarification; an explanation of why the request is rejected; the findings of a review; or a statement that more time is needed. The findings will include a description of the results and what level of correction will be made.

For appeals, a requester must submit an appeals package within 30 days following receipt of the official response. The appeal request will go one level higher, to the CIO. The CIO has another 60-day period for response, which will be either an answer to the request or a statement that more time is needed.

Dr. Seastrom acknowledged that this process is still at the theoretical stage, and that the real test will be "how we [DOE] end up operationalizing it, and work with program offices to process it."

Environmental Protection Agency

Ms. Barbara Pace noted that the guidelines were intended to provide guidance, not rules, and that the corrections process had been built on an existing process. Requests for corrections would be received and tracked by EPA's Office of Environmental Information.

The agency was still weighing the issue of information received from external sources (such as grantees), which she acknowledged to be "a tough one," and whether there should be time limits for corrections and appeals.

Requests for appeals would be received by the assistant administrator in charge of the program in question, who would make a decision with the help of an executive panel.

The agency will have a mechanism to filter out requests deemed to be frivolous or otherwise ineligible, and this, along with other features, would follow the notice and comment system already in place. "A separate appeals process isn't really necessary," she said, adding that while

some people had expressed a desire for one, they had offered few reasons why or how it would work. She said that the agency viewed it "as very difficult to establish a separate mechanism" for appeals.

An important consideration, she said, was to balance priorities and resources in meeting requests to correct completed products. "We may elect not to correct such things," she said. "Also, if we don't have a lot of detail on affected persons, it's not clear how we'll use that as a screening mechanism."

In commenting on reviewability of complaints by the courts, she suggested that it was not clear why the issuance of guidelines should change the existing landscape for judicial review. She said that the courts already take into account several factors, including standing, the nature of the action, and whether an action is final. Under existing law, the dissemination of information is not a reviewable action. "It is not clear that this would change the legal landscape," she said.

She concluded by saying that the variability among agency processes is not necessarily bad. Each agency would be expected to tailor its corrections process to their particular mission.

DISCUSSION

Mr. Anderson addressed the mechanism of answering requests for correction in the final rule. He suggested that seeking earlier opportunities to exchange information would provide "an opportunity to test it," which might be preferable to a potentially lengthy challenge process.

Mr. Ashby responded that agencies would still respond "to legitimate questions about data that will be used for rule making. It's just doing our job right. We'll go out and try to fix it."

Ms. Pace said that the testing of data is already built in to the EPA's notice and comment process, during which it issues notices of "data availability."

Laura Cleary, Public Citizen, asked what sort of administrative review would be required of agencies. Mr. Ashby replied that agencies may not have the obligation to correct certain information, such as "expensive" information, but suggested that there should be a "proportionality" in the appeals mechanism. That is, corrections deemed reasonable would be made, while those requiring significant resources might have to be reviewed individually.

A representative of the Natural Resources Defense Council asked about the EPA's intention to weave an appeal into their notice and comment process, and whether that would comply with the intentions of the Act. Mr. Ashby commented that the rules for handling an appeal through the Data Quality Act would be similar to those for handling an appeal

through the notice and comment process. For example, if a complaint were filed after the comment period expired, it would be filtered out. There already exist ways for outside parties to petition for reconsideration or amendment of a rule if, for example, it is based on inaccurate information. That can be processed as a petition to reconsider the rule itself. There also would be gray areas, Mr. Ashby said, in the case of information that is important to one or a few individuals but has little bearing on the validity of the rule.

One participant said that in the experience of his organization, the EPA may propose a rule and operate under it for a year or more before it becomes final. During the period before it is finalized, he said, the rule might cause harm if it were based on faulty data, and yet there was no appeal before finalization. Ms. Pace agreed that a proposed rule may be "out there for a while," but that she felt confident the existing appeals process would cover any valid complaints. Mr. Ashby said that a rule that had not yet been finalized would still be subject to the OMB guidelines, and that the only questions were the timing and process for responding.

SUBSTANTIVE ISSUES: "INFLUENTIAL" AND "QUALITY"

Department of Transportation

Mr. Robert Ashby noted the difficulty in determining whether information is "influential," which the OMB guidelines define as having a "clear and substantial impact" on decisions. Giving the results of his informal survey, Mr. Ashby said that the EPA had addressed this issue directly, listing categories of the most important agency actions, including those whose economic impact could be $100 million or more, or constituted the basis for new or revised policy. According to Mr. Ashby, some agencies had not attempted to define influential. Most assumed that certain kinds of information would be influential, given the mission of their particular agency. For example, the Department of Labor said that the Consumer Price Index and Producer Price Index were inherently influential. The State Department said "influential" information was a "narrow category" focused on "objective and quantifiable information forming the basis for policy decisions by the department."

For the DOT, Mr. Ashby said, a "clear and substantial" impact would be one that "the agency thinks has a high probability of occurring." He used the "clear and convincing" evidence standard as an analogy, which is "a little more than a preponderance," adding, "You want more than that."

Mr. Ashby noted that virtually every decision made by an agency is "important to someone." He cited the example of rust standards that are

set for highway bridge construction; such standards are of critical importance to members of an organization called the National Hot Dip Galvanizers Association, but to few other people. But for information to be "influential," it should be "outcome-determinative" for significant public- or private-sector rule-making, and must also concern scientific, statistical, or financial information, as described by OMB.

Beyond rule making, Mr. Ashby suggested that information will probably be considered influential if its effect is both broad and deep. For example, new standards for mammography would probably be influential because they would affect a great many people (breadth) for a compelling reason (depth). On the other hand, most decisions are either broad or deep, but not both. For example, the DOT's quarterly reports of on-time performance of airlines does not affect many individuals, although those companies affected place great importance on the results.

"Most of these will be judgment calls" by each agency, Mr. Ashby said, and some people will always disagree with those calls. As an aside, he noted that as stated in their comment letters, the position of the Chamber of Commerce was that all information pertaining to rule making should be considered influential; in another example, the American Bar Association did not agree with the use of an arbitrary line of $100 million in economic impact to determine influential information.

RISK ASSESSMENT

Food and Drug Administration

Dr. Jane Axelrad addressed the use of the Safe Drinking Water Act (SDWA) as a model for risk assessment in issues where safety is a central concern. She said that FDA strongly supports the OMB guidelines, which have "enough inherent flexibility" to allow the agency to implement them in ways that are helpful to its mission.

Dr. Axelrad suggested that each agency would likely use its own template for risk assessment, tailored to its particular needs. The FDA, for example, must use qualitative judgments and balance risks against benefits in regulating the manufacture and use of drugs, cosmetics, animal feed, and other products. The agency also must decide what information ought to be included in drug labeling and how that information should be organized. Such actions do not lend themselves to the quantitative risk assessment used in SWDA, and it may be difficult to prove that the information is of high quality. In a risk/benefit environment, the use of peer review, as modeled in SDWA standards, is problematic, both because there may be no single "right" answer to an evaluation, and because much

of the information used by FDA is received from third parties that prohibit data sharing for proprietary reasons.

As a result, the FDA will adapt SDWA to meet its special needs by using the following criteria for product approvals and other kinds of *qualitative* risk assessments:

- Use the best available science and supporting studies, including peer review when possible;
- Use data collected by accepted methods; and
- Ensure that information disseminated publicly about risks is clear.

The agency uses the following criteria for risk assessment that can be *quantitative*:

- The three criteria listed above;
- State appropriate upper-bound and/or lower-bound risk estimates;
- Identify data gaps, other significant uncertainties;
- Identify studies that would assist in reducing data gaps and uncertainties; and
- Identify additional studies that support or fail to support the findings of the assessment and explain why they were not used.

Dr. Axelrad concluded by saying that the FDA had received few comments about its proposed guidelines.

DISCUSSION

Mr. Goldberg of the Mitre Corporation asked how agencies should handle intramural data created for its own purposes but later expected to become influential. Dr. Axelrad said that FDA hadn't yet confronted that situation, but that influential information would usually be identified when it was prepared for dissemination. She said that staff in program offices will have to be aware of information that might be influential at a later date.

Frederick Anderson returned to the issue of data quality, asking whether it was not better to "clear up questions about data before the potentially lengthy process of rule making. "Unless you seek opportunities to exchange data," he said, "you're missing opportunities to test it." He asked whether it would be a good idea to have a pre-rule data identification and challenge process. Dr. Axelrad said that an agency already will respond to legitimate questions about data that will be used for rulemaking. Ms. Pace added that the EPA already does this when it issues notices of data availability. "Anything we do would have to go into the

notice and comment process anyway," she said. Mr. Ashby said that the OMB guidelines were "really an embellishment on the original statute." On the low end, a properly framed appeal for information might function as a due diligence check—that is, did the agency in fact follow proper procedures in producing the information. For more serious appeals, the level of review would rise. "We suggest that there be a built-in proportionality," Mr. Ashby added.

Evaluation of Several Agency Guidelines

Representatives of several scientific societies offered brief evaluations of the guidelines of agencies they followed or worked with.

Federation of American Societies of Experimental Biology (FASEB)

Dr. Howard Garrison offered an assessment of the draft guidelines adopted by two agencies, the NIH and NSF. Both, he said, "responded responsibly," while showing "striking differences" because of their different missions.

The NSF focused on its dissemination of substantive information, especially scientific reports, program summaries, and reports used for policy. They omitted information gathered by grantees. The NSF assessed the utility of its data programs regularly by external review panels and assured objectivity through rigorous statistical methods, which led to good reproducibility. Not all statistical summaries were reproducible by outside parties due to confidentiality, but the NSF had "strong guidelines and a distinguished tradition" for producing such documents and for setting a standard for other agencies. The cost of this quality was often high in terms of timeliness, he said, citing a report he had just received that was based on data collected in fall 2000—a year and a half earlier. At the same time, the report was a "model of transparency," showing detailed methodologies, clear presentation for both lay and professional audiences, wide availability in print and electronic forms, with "exemplary" summaries and statistical tables of report.

The NIH, Dr. Garrison said, faced a more complex challenge, with its 27 institutes and centers. The guidelines differed somewhat for each entity, and were tied to their different products. They were based on existing quality assurance programs, and limited to information used for official NIH statements. Information from grantees was not covered. Nonetheless the guidelines covered a large amount of information, including more than 400 publications per year, and a hundred thousand pages of material on the Web site. All of it had been subjected to peer and internal review. Studies deemed influential received three checks, to en-

sure (1) exemplary data quality, (2) transparency, through references, documentation, disclosure of potential sources of error, and disclaimers, and (3) peer review, considered the most important check. He noted that scientists view peer review as an integral feature of quality assurance. When scientists prepare papers, they build in careful documentation of their procedures to prevent misunderstandings.

In conclusion, said Dr. Garrison, both agencies had developed comprehensive policies to demonstrate the quality of the data they disseminated, as well as mechanisms for addressing challenges and providing reasonable avenues for affected parties to request corrections.

American Institute of Biological Sciences

Ms. Ellen Paul reviewed the responses to OMB guidelines by the USDA and the Department of the Interior.

The USDA, she said, had considered both internally and externally produced information under the four OMB standards (objectivity, reproducibility, utility, integrity). But she also raised several areas for improvement. Reproducibility had not been addressed, she said, nor had the issue of what was influential. More serious, she said, was that the agency had proposed consulting with potential users in advance of undertaking a research project. "One can imagine that some users would say, don't do the study at all if it may result in a regulation they don't want. There is nothing in the guidelines to resolve that." She added that such an approach would also neglect the USDA's internal needs.

Ms. Paul also said that in the agency's discussion of risk assessment, one would expect some mention of the Safe Drinking Water Act standards; this did not appear, nor was there any other discussion of risk assessment, the use of models, or how the use of models would be affected by the guidelines. Finally, she said that for its correction process, the agency had "put the burden of proof on the complainant." Also, the agency's requirements in the correction process were not legally binding,[1] and a challenge could be filed at any time without penalty. There was no

[1]While an agency may agree that the data are incorrect, the agency is not legally required to change the data. As Ms. Paul noted, many factors can influence whether an agency decides to correct information following a complaint. In summarizing his informal survey of agencies, Robert Ashby of the Department of Transportation said that agencies might agree that some information could be improved, but would correct it only if it would serve a "useful purpose." Some corrections would require significant resources or might not advance the material interest of the public or the requester. "You don't want the correction process driving your budget," said Mr. Ashby.

anticipation that complaints might be filed ad seriatim for months or years.[2]

Turning to the Department of Interior guidelines, Ms. Paul said that most of the department's primary research was done by the U.S. Geological Survey, and most of that was intramural. Other bureaus published information, but did not have the capacity for the kind of review contemplated by the OMB guidelines. The department's guidelines, she said, were limited to two points: first, the agency would do what the OMB requested, and second, it would instruct departmental bureaus to implement the guidelines. This response did not address the issue of different kinds of research (funded, contractor, grantee), and did not address the four standards individually, except to repeat the OMB definitions.

The DOI guidelines did address data quality procedures, but she criticized the agency's response for not anticipating issues that might arise during challenges, especially the right of the researcher to respond. Ms. Paul suggested that the prospect of unlimited challenges by people trying to obstruct research would likely dissuade talented young researchers from joining the department.

American Association for the Advancement of Science (AAAS)

Dr. Joanne Carney reviewed two agencies, the NSF and EPA. She said that in her view both agencies seemed to provide transparency. She added that the AAAS placed high value on peer review in its own work. Peer review achieved transparency by substantiating the data and controls, and by explaining uncertainties behind the data.

For NSF, Dr. Carney said she agreed with the opinion of Dr. Garrison. The agency was clear about its processes, and the ways it verified the utility and objectivity of its information. It was clear in saying that grantees have sole responsibility for preparing their own information. For statistical data, NSF is clear about its methods of collection, sources, and limitations. She said that the AAAS is a regular user of NSF data, which it found to be of high quality, if not always as timely as some users would like.

The EPA had recently held both a public meeting and an online comment period in regard to its guidelines. Dr. Carney noted that EPA's guidelines were a "thorough job, given the nature of the work they do and the products they provide." She said it was important for the EPA to clearly articulate that the guidelines are not intended to replace existing procedures or statutory guidelines. Existing procedures already provide

[2]Several speakers noted the possibility that serial suits could be used as a harassment tactic to encumber research and ultimately delay agency action.

for public comment and requests for correction. EPA had already clarified that extramural researchers were responsible for deciding how to publish research results that were not associated with agency policy – a "separation of church and state." She cautioned that the agency should take care not to let guidelines "overly hamper" the pursuit of basic research. She said that the agency provided a disclaimer saying that for information initially not covered under guidelines (produced before October 1, 2002), and then disseminated after October 1, 2002, the agency should try to ensure that such information is reproducible and otherwise of high quality.

The EPA addressed the category of "influential" information, including a case-by-case analysis and a description of the existing standard of information that might have economic significance of $100 million or more. Dr. Carney said that the first category of influential was overly broad: that is, information disseminated "in support of top agency actions" was not defined. Also, the agency acknowledged that the issue of third-party data is controversial. Such data should still be utilized, but the confidentiality of the researcher needs to be observed. Some individuals have claimed that EPA is "hiding behind those confidentiality laws," but she added that one can "still look at analytical results without violating confidentiality." She agreed with EPA that often one must use the "best available" information, because science is an ongoing process that does not achieve answers that are final or fixed. "We will know more as scientific research moves forward. But sometimes we have to look at what's available today and make a decision. The EPA did a good job there."

Dr. Carney concluded by saying that EPA needs to be more specific about its time limits for correction requests, and how a petitioner has to demonstrate being harmed by the information. These guidelines need to be clear, she said, or the agency will be "overburdened."

Next Steps in the Data Quality Process

Over the course of the Spring and Summer 2002, agencies will receive comments from the public and will work with OMB on revising and finalizing their agency-specific guidelines. OMB's Guidelines go into effect on October 1, 2002.

Appendixes

Appendix A

Ad Hoc Committee Members' Biographies

Cochair, **David Korn, (IOM)**, M.D., Harvard, is Senior Vice President for Biomedical and Health Sciences Research, Association of American Medical Colleges, in Washington, D.C. Previously, he served as Dean of Stanford University School of Medicine.

Cochair, **Alan B. Morrison**, L.L.B., Harvard Law School, is Irvine Visiting Fellow, Stanford University Law School, Palo Alto, CA, on leave as Director, Public Citizen Litigation Group, Washington, D.C. Public Citizen, Inc., is a non-profit citizen research, lobbying and litigation organization.

Frederick R. Anderson, J.D., Harvard Law School, is a partner at Cadwalader, Wickersham & Taft in Washington, D.C. He is a former Dean of the Washington College of Law at American University. He was a member of the NAS planning committee that initiated the 1997 Academy Symposium on Science, Technology, and Law.

Joel E. Cohen, (NAS), Dr.P.H., population sciences and tropical public health, and Ph.D., applied mathematics, Harvard, is the Abby Rockefeller Mauze Professor and Head, Laboratory of Populations, The Rockefeller University and Professor of Populations, Columbia University, in New York City. From 1991-1995, Dr. Cohen served as a U.S. Federal Court-appointed neutral expert on projections of asbestos-related claims associated with the Manville Personal Injury Settlement Trust. In addition, he has served as a Special Master in silicone gel breast implant products liability.

Donald Kennedy (NAS/IOM), Ph.D. (biology), Harvard, is Bing Professor of Environmental Sciences and co-director, Center for Environmental Science and Policy, Institute for International Studies, Stanford University. He is President Emeritus of Stanford University. He also serves as Editor in Chief, *Science*. He served as Commissioner of the U.S. Food and Drug Administration. He was a member of the NAS planning committee that initiated the 1997 Academy Symposium on Science, Technology, and Law.

Richard A. Merrill (IOM), L.L.B., Columbia University School of Law, is the Daniel Caplin Professor of Law at the University of Virginia Law School. From 1975-1977 he served as Chief Counsel to the U.S. Food and Drug Administration. He was Dean of the University of Virginia Law School from 1980 to 1988. Since 1991 he has been special counsel to Covington & Burling. He was a member of the NAS planning committee that initiated the 1997 Academy Symposium on Science, Technology, and Law.

Staff

Anne-Marie Mazza, Ph.D., Director. Dr. Mazza joined The National Academies in 1995. She has served as Senior Program Officer with both the Committee on Science, Engineering, and Public Policy and the Government-University-Industry Research Roundtable. Between October 1999 and October 2000, she divided her time between the STL Program and the White House Office of Science and Technology Policy, where she chaired an interagency working group on the government-university research partnership. She received a Ph.D. in Public Policy from The George Washington University.

Susie Bachtel, Staff Associate. Ms. Bachtel joined the National Academies in 1998. Previously she was Special Assistant to the Director, White House Office of Science and Technology Policy, from 1993-1998, and before that was Executive Assistant to the Director of the U.S. Office of Technology Assessment from 1979-1993. She received a B.A. in Social Sciences from The Ohio State University.

Alan Anderson, Consultant Writer. Mr. Anderson has written National Academy reports on a variety of topics. He also writes for the Institute for Advanced Study in Princeton, N.J., and other clients. He has been a science writer for *Time* magazine and other publications, and holds a master's degree from the Columbia University School of Journalism and a B.A. in English from Yale University.

Appendix B

Science, Technology, and Law Panel Biographies

Cochair: **Donald Kennedy (NAS/IOM),** Ph.D. (biology), Harvard, is Bing Professor of Environmental Sciences and co-director, Center for Environmental Science and Policy, Institute for International Studies, Stanford University. He is President Emeritus of Stanford University. He also serves as Editor in Chief, *Science*. He served as Commissioner of the U.S. Food and Drug Administration. He was a member of the NAS planning committee that initiated the 1997 Academy Symposium on Science, Technology, and Law.

Cochair: **Richard A. Merrill (IOM)**, L.L.B., Columbia University School of Law, is the Daniel Caplin Professor of Law at the University of Virginia Law School. From 1975-1977 he served as Chief Counsel to the U.S. Food and Drug Administration. He was Dean of the University of Virginia Law School from 1980 to 1988. Since 1991 he has been special counsel to Covington & Burling. He was a member of the NAS planning committee that initiated the 1997 Academy Symposium on Science, Technology, and Law.

Frederick R. Anderson, J.D., Harvard Law School, is a partner at Cadwalader, Wickersham & Taft in Washington, D.C. He is a former Dean of the Washington College of Law at American University. He was a member of the NAS planning committee that initiated the 1997 Academy Symposium on Science, Technology, and Law.

Margaret A. Berger, J.D. , Columbia University, is the Suzanne J. and Norman Miles Professor of Law at Brooklyn Law School in Brooklyn, New

York. She has written extensively on science and law, and in particular on three key Supreme Court cases (*Daubert, Joiner, Kumho*) dealing with evidence. She is the co-author of Weinstein's *Evidence*.

Paul Carrington, L.L.B., Harvard, is the Harry R. Chadwick Senior Professor at Duke University Law School. He is the former Dean of Duke's Law School and has taught and published extensively on civil procedures. He was Reporter to the Advisory Committee on Civil Rules of the Judicial Conference of the United States. He also established the Private Adjudication Center, which developed a Registry of Independent Scientists to provide disinterested advice to lawyers and judges on scientific issues that are the subject of legal disputes.

Joe S. Cecil, Ph.D., psychology, and J.D., Northwestern University, is Project Director, Program on Scientific and Technical Evidence, Division of Research, Federal Judicial Center, in Washington, D.C. He is responsible for judicial education and training in the area of scientific and technical evidence and the lead staff of the Federal Judicial Center's Scientific Evidence Manual, which is the primary source book on evidence for federal judges.

Joel E. Cohen, (NAS), Dr.P.H., population sciences and tropical public health, and Ph.D., applied mathematics, Harvard, is the Abby Rockefeller Mauze Professor and Head, Laboratory of Populations, The Rockefeller University and Professor of Populations, Columbia University, in New York City. From 1991-1995, Dr. Cohen served as a U.S. Federal Court-appointed neutral expert on projections of asbestos-related claims associated with the Manville Personal Injury Settlement Trust. In addition, he has served as a Special Master in silicone gel breast implant products liability.

Rebecca S. Eisenberg, J.D., is a Professor of Law at the University of Michigan in Ann Arbor, Michigan. Ms. Eisenberg teaches courses in intellectual property and torts and has taught on legal regulation of science and on legal issues associated with the Human Genome Project.

David Goodstein, Ph.D., physics, University of Washington, is Vice Provost and Professor of Physics and Applied Physics at the California Institute of Technology. His book, *States of Matter*, helped launch a new discipline, condensed matter physics. In recent years, he has been particularly interested in societal issues that affect science as a profession.

Barbara S. Hulka, (IOM), M.D., Columbia College of Physicians and Surgeons, is Kenan Professor, Department of Epidemiology, School of Public

Health, University of North Carolina at Chapel Hill. Dr. Hulka's current research activities are in the field of cancer epidemiology—breast, uterine and prostate—and the application of biological markers to cancer epidemiology. Dr. Hulka is working on the development of a process for incorporating scientific data into the judicial system.

Sheila Jasanoff, Ph.D., Harvard, J.D., Harvard, is Professor of Science and Public Policy at Harvard University's John F. Kennedy School of Government and the School of Public Health. Jasanoff's long-standing research interests center on the interactions of law, science, and politics in democratic societies. She is the author of numerous papers and books including, *The Fifth Branch: Science Advisors as Policymakers,* and *Science at the Bar: Law, Science, and Technology in America.*

Robert E. Kahn, **(NAE)**, Ph.D., Electrical Engineering, Princeton University, is Chairman, CEO and President of the Corporation for National Research Initiatives (CNRI), a not-for-profit organization that provides funding and leadership to the research and development of the National Information Infrastructure. Dr. Kahn is a co-inventor of the TCP/IP protocols and a recipient of the 1997 National Medal of Technology awarded by President Clinton.

Daniel J. Kevles, Ph.D., History, Princeton, is the Stanley Woodward Professor of History, at Yale University. Prior to this he was the Koepfli Professor of Humanities and directed the Program in Science, Ethics, and Public Policy at the California Institute of Technology in Pasadena, California. He has written extensively on issues regarding science and society including genetics, patenting, and scientific misconduct.

David Korn, (IOM), M.D., Harvard, is Senior Vice President for Biomedical and Health Sciences Research, Association of American Medical Colleges, in Washington, D.C. Previously, he served as Dean of Stanford University School of Medicine.

Eric S. Lander, (NAS/IOM), D.Phil., mathematics, Oxford University, is Member, Whitehead Institute for Biomedical Research, Professor of Biology, MIT, Director, Whitehead Institute/MIT Center for Genome Research, and Geneticist, Massachusetts General Hospital, Massachusetts Institute of Technology in Cambridge, Massachusetts. He is a geneticist, molecular biologist, and a mathematician, with research interests in human genetics, mouse genetics, population genetics, and computational and mathematical methods in biology. He also has taught in the area of management and economics. Dr. Lander is a member of the American

Academy of Forensic Sciences and has written about DNA fingerprinting and other issues of science and law.

Patrick A. Malone, J.D., Yale Law School, is a partner with Stein, Mitchell & Mezines in Washington, D.C. Mr. Malone, a former medical journalist, represents plaintiffs in medical malpractice and product liability lawsuits. He is a member of the Association of Trial Lawyers of America and Trial Lawyers for Public Justice.

Richard A. Meserve, Ph.D., applied physics, Stanford, J.D., Harvard, is Chairman of the Nuclear Regulatory Commission. Prior to his appointment he was a partner with the Washington, D.C. firm Covington and Burling, where he represented a number of corporate and non-corporate clients. Dr. Meserve earned both a J.D. and a Ph.D. He was a member of the NAS planning committee that initiated the 1997 Academy Symposium on Science, Technology, and Law. He wrote the *amicus* briefs on behalf of the National Academy of Engineering in the *Kumho* case and on behalf of the National Academy of Sciences in the *Daubert* case. These landmark cases established the basis for admitting expert testimony into court.

Alan B. Morrison, L.L.B., Harvard Law School, is Irvine Visiting Fellow, Stanford University Law School, Palo Alto, CA, on leave as Director, Public Citizen Litigation Group, Washington, D.C. Public Citizen, Inc., is a non-profit citizen research, lobbying, and litigation organization.

Harry J. Pearce, J.D., Northwestern University School of Law, is Chairman of Hughes Electronics Corporation, a subsidiary of General Motors Corporation in El Segundo, California. He previously served General Motors as Vice Chairman, and prior to that as General Counsel. Mr. Pearce has been admitted to the U.S. Supreme Court, U.S. Court of Military Appeals, Eight Circuit Court of Appeals, various U.S. District Courts and State District Courts and the Michigan Supreme Court.

Henry Petroski, **(NAE)**, Ph.D., University of Illinois, is the A.S. Vesic Professor of Civil Engineering, Duke University in Durham, North Carolina. He has been very involved in engineering and law issues. Most recently, he authored a chapter on engineering expert testimony for the Federal Judicial Center's evidence project.

Channing R. Robertson, Ph.D., Chemical Engineering, is the Ruth G. and William k. Bowes Professor, School of Engineering, and Professor, Department of Chemical Engineering, Stanford University. Dr. Robertson

conducted research on several products in which there was extensive litigation and in which he served as an expert.

Pamela Ann Rymer, L.L.B., Stanford, is a Circuit Judge on the U.S. Court of Appeals for the Ninth Circuit in Pasadena, California. She was appointed in 1989 by President George Bush. Judge Rymer currently serves as the Chair of the AAAS Court-Appointed Scientific Experts Demonstration Project.

Staff of the Science, Technology, and Law Program

Anne-Marie Mazza, Ph.D., Director. Dr. Mazza joined The National Academies in 1995. She has served as Senior Program Officer with both the Committee on Science, Engineering and Public Policy and the Government-University-Industry Research Roundtable. Between October 1999 and October 2000, she divided her time between the STL Program and the White House Office of Science and Technology Policy, where she chaired an interagency working group on the government-university research partnership. She received a Ph.D. in Public Policy from The George Washington University.

Susie Bachtel, Staff Associate. Ms. Bachtel joined the National Academies in 1998. Previously she was Special Assistant to the Director, White House Office of Science and Technology Policy, from 1993-1998, and before that was Executive Assistant to the Director of the U.S. Office of Technology Assessment from 1979-1993. She received a B.A. in Social Sciences from The Ohio State University.

Appendix C

Workshop Meeting Agendas

MARCH 21, 2002
MARCH 22, 2002
MAY 30, 2002

ENSURING THE QUALITY OF DATA DISSEMINATED BY THE FEDERAL GOVERNMENT

Science, Technology, and Law Program
The National Academies
Auditorium
Workshop #1

March 21, 2002

8:30 *Welcome*
Richard A. Merrill
Daniel Caplin Professor of Law and Sullivan and Cromwell Research Professor of Law
University of Virginia Law School
Cochair, Science, Technology, and Law Program

8:40 *Opening Remarks*
John D. Graham
Administrator
Office of Information and Regulatory Affairs
U.S. Office of Management and Budget

9:00 *Session 1: Meaning and Intent/Scope and Applicability—OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*

Alan B. Morrison
Irvine Visiting Fellow, Stanford University School of Law
Cochair, Ad Hoc Committee on Data Quality

10:00 *Question Period*
Agencies
Public

10:40 *Break*

11:00 *Session 2: Handling Complaints—The Administrative Correction and Appeals Mechanisms*

Moderator
Frederick R. Anderson
Cadwalader, Wickersham & Taft

Speakers
Daniel Cohen
Chief Counsel for Regulation
Office of the General Counsel
U.S. Department of Commerce

Elaine G. Stanley
Director
Office of Environmental Information
U.S. Environmental Protection Agency

Neil R. Eisner
Assistant General Counsel
Office of the General Counsel
U.S. Department of Transportation

James Scanlon
Director, Division of Data and Information Policy
Office of the Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services

12:00 *Question Period*
Agencies
Public

12:40 *Lunch*

2:00 *Session 3: Determining the Threshold - Influential Scientific, Statistical, and Financial Information*

Moderator

Richard A. Merrill
Daniel Caplin Professor of Law and Sullivan and Cromwell Research Professor of Law, University of Virginia Law School
Cochair, Science, Technology, and Law Program

Speaker

Richard J. Pierce, Jr.
Lyle T. Alverson Professor of Law
The George Washington University Law School

2:20 *Agency Approaches*

Speakers

Nancy Kirkendall
Director
Statistics and Methods Group
Energy Information Administration
U.S. Department of Energy

Steven Galson
Deputy Director
Center for Drug Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Services

Fred Siskind
Economist
Office of the Assistant Secretary for Policy
U.S. Department of Labor

2:55 *Question Period*
Agencies
Public

3:30 *Adjourn*

Ensuring the Quality of Data Disseminated by the Federal Government
Science, Technology, and Law Program
The National Academies
Auditorium
Workshop #2

March 22, 2002

8:30 *Session 1: The Standards of Transparency/Reproducibility/Peer Review for Influential Information*

Moderator
Michael R. Taylor
Senior Fellow and Director, Risk Resource, and Environmental Management
Resources for the Future

Speakers
Robert M. O'Keefe
Vice President
Health Effects Institute

R. Brooks Hanson
Deputy Managing Editor for Physical Sciences
Science

9:05 *Agency Approaches*

Speakers
Heather G. Miller
Senior Advisor to the Deputy Director for Extramural Research
National Institutes for Health
U.S. Department of Health and Human Services

Kevin Y. Teichman
Associate Director for Science
Office of Science Policy
Office of Research and Development
U.S. Environmental Protection Agency

John M. Rodgers
Director
Office of Aviation Policy and Plans
Federal Aviation Administration
U.S. Department of Transportation

9:50 *Question Period*
Agencies
Public

10:20 *Break*

10:45 *Session 2: Risk Information Regarding Human Health, Safety, and the Environment*

Moderator
Joe Cecil
Project Director
Research Division
Federal Judicial Center

Speaker
Joseph V. Rodricks
Principal
ENVIRON International Corporation

11:15 *Adopting or Adapting the SDWA Standards: Agency Approaches*

Speakers
William Perry
Director
Office of Risk Reduction Technology
Directorate of Health Standards Program
Occupational Safety and Health Administration
U.S. Department of Labor

Steven Galson
Deputy Director
Center for Drug Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Services

11:45 *Question Period*
Agencies
Public

12:15 *Adjourn*

Ensuring the Quality of Data Disseminated by the Federal Government
Science, Technology, and Law Program
The National Academies
Main Auditorium
Workshop #3: Agency-Specific Guidelines

May 30, 2002

8:30 Registration/Continental Breakfast

9:00 *Scientific Societies—Perspectives on Agency-Specific Guidelines*

Moderator
Richard A. Merrill
Daniel Caplin Professor of Law and
Sullivan and Cromwell Research Professor of Law
University of Virginia Law School
Cochair Science, Technology, and Law Program

Howard Garrison
Director of Public Affairs
Federation of American Societies for Experimental Biology

Ellen Paul
Public Policy Representative
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Joanne P. Carney
Director
Center for Science, Technology, and Congress
American Association for the Advancement of Science

9:30 *Session 1: Scope and Coverage*
Moderator
Alan B. Morrison
Irvine Visiting Fellow, Stanford University School of Law
Co-chair, Ad Hoc Committee on Data Quality

Agency Presentations

Lisa K. Westerback
Director, Office of Information Policy, Planning, and Review
Office of Chief Information Officer
U.S. Department of Commerce

James Scanlon
Director, Division of Data and Information Policy
Office of the Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services

10:10 *Questions/Comments*

10:30 *Session 2: Correction and Appeals Process*

Moderator

Frederick R. Anderson, Jr.
Partner
Cadwalader, Wickersham & Taft

Agency Presentations

Robert C. Ashby
Deputy Assistant General Counsel for Regulation and Enforcement
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Chief Statistician
National Center for Education Statistics
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Barbara Pace
Senior Attorney, Cross-Cutting Issues Law Office
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11:10 *Questions/Comments*

11:30 *Session 3: Substantive Issues*

Moderator
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Influential
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SDWA:Adopt/Adapt
Jane A. Axelrad
Associate Director for Policy
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12:10 *Questions/Comments*

12:30 *Lunch/Adjourn*

Appendix D

Combined Registrants:

WORKSHOP #1: MARCH 21, 2002
WORKSHOP #2: MARCH 22, 2002
WORKSHOP #3: MAY 30, 2002

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